

CLAIMS:

1. A microneedle device comprising:
a substrate comprising a first major surface; and
at least one microneedle projecting from the first major surface of the substrate, the
5 at least one microneedle comprising a base proximate the first major surface of the
substrate, wherein the at least one microneedle is tapered from the base to a flat tip distal
from the base such that the at least one microneedle comprises a truncated tapered shape;
wherein the flat tip comprises a surface area measured in a plane aligned with the
base of 20 square micrometers or more and 250 square micrometers or less.
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2. A device according to claim 1, wherein the at least one microneedle comprises a
plurality of microneedles.
3. A device according to claim 1, wherein the flat tip comprises a surface area of 100
15 square micrometers or less.
4. A device according to claim 1, wherein the flat tip comprises a surface area of 50
square micrometers or less.
- 20 5. A device according to claim 1, wherein the at least one microneedle comprises a
height above the first major surface and a maximum base dimension, the height and the
maximum base dimension ratio defining an aspect ratio, wherein the aspect ratio is 2:1 or
more.
- 25 6. A device according to claim 1, wherein the at least one microneedle is formed of
one or more polymers.
7. A device according to claim 1, wherein the base of the at least one microneedle
comprises a base area of 900 square micrometers or more.

8. A microneedle device comprising:

a substrate comprising a first major surface; and

a plurality of microneedles projecting from the first major surface of the substrate,

each microneedle of the plurality of microneedles comprising a base proximate the first major surface of the substrate, wherein each microneedle of the plurality of microneedles is formed of one or more polymers and is tapered from the base to a flat tip distal from the base such that each microneedle of the plurality of microneedles comprises a truncated tapered shape;

wherein the flat tip comprises a surface area measured in a plane aligned with the base of 20 square micrometers or more and 100 square micrometers or less;

wherein the base of each microneedle of the plurality of microneedles comprises a base area of 900 square micrometers or more;

and wherein each microneedle of the plurality of microneedles comprises a height above the first major surface and a maximum base dimension, the height and the maximum base dimension ratio defining an aspect ratio, wherein the aspect ratio is 3:1 or more.

9. A microneedle device comprising:

a substrate comprising a first major surface; and

at least one microneedle projecting from the first major surface of the substrate, the at least one microneedle comprising a base proximate the first major surface of the substrate, wherein the at least one microneedle is tapered from the base to a tip distal from the base such that the at least one microneedle comprises a truncated tapered shape having a height (h) above the first major surface as measured from the base to the tip;

wherein the at least one microneedle comprises a cross-sectional area of 20 square micrometers or more and less than a base area of the at least one microneedle, where the cross-sectional area is measured in a plane aligned with the base, the plane being located at a distance of 0.98h from the base.

10. A device according to claim 9, wherein the at least one microneedle comprises a plurality of microneedles.

11. A device according to claim 9, wherein the cross-sectional area comprises 25% or less of the base area.

12. A device according to claim 9, wherein the cross-sectional area comprises 100 square micrometers or less.

13. A device according to claim 9, wherein the at least one microneedle comprises a height (h) above the first major surface and a maximum base dimension, the height and the maximum base dimension ratio defining an aspect ratio, wherein the aspect ratio is 2:1 or more.

14. A device according to claim 9, wherein the at least one microneedle is formed of one or more polymers.

15. A device according to claim 9, wherein the base of the at least one microneedle comprises a base area of 900 square micrometers or more.

16. A microneedle device comprising:
a substrate comprising a first major surface; and
a plurality of microneedles projecting from the first major surface of the substrate, each microneedle of the plurality of microneedles comprising a base proximate the first major surface of the substrate, wherein each microneedle of the plurality of microneedles is formed of one or more polymers and is tapered from the base to a flat tip distal from the base such that each microneedle of the plurality of microneedles comprises a truncated tapered shape;

wherein each microneedle of the plurality of microneedles comprises a cross-sectional area of 20 square micrometers or more and 25% or less of a base area of each

microneedle of the plurality of microneedles, where the cross-sectional area is measured in a plane aligned with the base, the plane being located at a distance of $0.98h$ from the base;

wherein the base of each microneedle of the plurality of microneedles comprises a base area of 900 square micrometers or more;

5 and wherein each microneedle of the plurality of microneedles comprises a maximum base dimension, the height and the maximum base dimension ratio defining an aspect ratio, wherein the aspect ratio is 3:1 or more.

17. A method of using a microneedle device, the method comprising:

10 providing a microneedle device according to claim 1;
 contacting skin on a patient with the at least one microneedle;
 forcing the microneedle device against the skin.

18. A method of using a microneedle device, the method comprising:

15 providing a microneedle device according to claim 9;
 contacting skin on a patient with the at least one microneedle;
 forcing the microneedle device against the skin.

19. A method of delivering a microneedle device, the method comprising:

20 positioning a microneedle device proximate a delivery site on skin, the microneedle array comprising a plurality of microneedles protruding from a surface; and
 accelerating a piston comprising a face towards the microneedle device, wherein the piston comprises a minimum velocity of 4 meters per second or more and a maximum velocity of 10 meters per second or less when the face of the piston contacts the
25 microneedle device.

20. A method according to claim 19, further comprising forcing a pressure collar against the skin around the microneedle device.

21. A method according to claim 20, wherein the pressure collar is located on a housing that also comprises the piston and a driver operably connected to the piston, the driver providing acceleration of the piston.
- 5 22. A method according to claim 19, wherein the minimum velocity is 6 meters per second or more.
23. A method according to claim 19, wherein the maximum velocity is 8 meters per second or less.
- 10 24. A method according to claim 19, wherein the piston comprises a mass of 4 grams or less.
- 15 25. A method according to claim 19, wherein the piston comprises a mass of 2 grams or less.
26. A method according to claim 19, further comprising marking the delivery site with a marking composition.
- 20 27. A method of delivering a microneedle device, the method comprising:
providing a microneedle delivery apparatus comprising a microneedle device comprising a plurality of microneedles protruding from a surface, the microneedle device being attached to a face of a piston, a driver operably connected to the piston; and
accelerating the piston and the attached microneedle device towards the delivery
25 site using the driver, wherein the piston comprises a minimum velocity of 4 meters per second or more and a maximum velocity of 10 meters per second or less when the microneedle device contacts the delivery site.
- 30 28. A method according to claim 27, further comprising marking the delivery site with a marking composition.

29. A method according to claim 27, wherein the microneedle delivery apparatus comprises a pressure collar located on an exterior of the microneedle delivery apparatus, and wherein the method further comprises contacting the pressure collar to skin around a delivery site.

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30. A method according to claim 29, wherein the pressure collar is located on a housing that contains the piston and the driver.

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31. A method according to claim 27, wherein the minimum velocity is 6 meters per second or more.

32. A method according to claim 27, wherein the maximum velocity is 8 meters per second or less.

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33. A method according to claim 27, wherein the piston and the attached microneedle device comprise a combined mass of 4 grams or less.

34. A method according to claim 27, wherein the piston and the attached microneedle device comprise a combined mass of 2 grams or less.

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35. A method of delivering a drug, the method comprising:
positioning a microneedle device proximate a delivery site on skin, the microneedle device comprising a plurality of microneedles protruding from a surface;
accelerating a piston comprising a face towards the microneedle device, wherein the piston comprises a minimum velocity of 4 meters per second or more and a maximum velocity of 10 meters per second or less when the face of the piston contacts the microneedle device;
removing the microneedle device from the delivery site; and
applying a drug to the delivery site.

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36. A method according to claim 35, wherein the drug is formulated into a delivery vehicle.

5 37. A method according to claim 36, wherein the delivery vehicle is a solution, cream, or adhesive matrix.

38. A method according to claim 35, wherein the drug is an ionic molecule.

10 39. A method according to claim 38, wherein the drug is sodium alendronate.

40. A method according to claim 35, wherein the drug is a vaccine adjuvant.